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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,320	02/13/2001	Bernhard H. van Lengerich	BVL-102A	9819

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EXAMINER	
ROBERTS, LEZAH	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/782,320	VAN LENGERICH, BERNHARD H.	
	Examiner	Art Unit	
	LEZAH W. ROBERTS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *94* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-31, 34, 35, 37-40, 42, 46, 50, 52-59, 61, 62, 64-67, 69, 70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103, 105 and 108-110* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 25-31, 34, 35, 37-40, 42, 46, 50, 52-59, 61, 62, 64-67, 69, 70, 73, 75, 79, 81-85, 91-97, 101, 103, 105 and 108-110.

DETAILED ACTION

Applicants' arguments, filed January 15, 2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This Action is made NON-FINAL.

Claims

Claim Rejections - 35 USC § 112 – Written Description (Previous Rejection)

Claims 31, 59, 108 and 109 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's Arguments

Applicant argues polyvinyl acetate and derivatives thereof, and modified starches are well known to those skilled in the art, as evidenced by Newton et al (USP 4,938,967) at col. 8 lines 61-65, and col. 9 lines 18-29, and Wittwer et al (USP 4,738,724) at col. 7 line 67 to col. 8 line 24. Those skilled in the art would be able to select numerous polyvinyl acetate derivatives or modified starches from known compounds which may be employed to make and use the claimed invention using the disclosure as a guide.

Examiner's Response

Although Newton et al. and Wittwer disclose terms such as derivatives, they do not provide examples of what is encompassed by these terms in such a way that would apprise one to know what compounds are encompassed by Applicant's of derivatives and modified starches and when a compound is modified to a degree where it is no longer considered a derivative or modified compound of the parent compound. Thus, the instant specification is unclear and does not define at what point does modifying the core compound lead to different compound that would not be considered a derivative or modified starch encompassed by the instant invention.

Claim Rejections - 35 USC § 112 – Indefiniteness (Previous Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25, 27-31, 34, 35, 37, 38, 42, 46, 52-59, 61, 62, 64-67, 69, 70, 73, 75, 79, 82, 83, 91-93 and 95-97 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is maintained and further applied to claims 26, 50, 108 and 109.

Applicant's Arguments in regards to "substantially"

Applicant argues the term "substantially" makes it clear that the terms it is used in conjunction with should not be interpreted as requiring perfection or an ideal, and that variations, which do not adversely affect desired release properties of the product, may be included. Those skilled in the art would know what is meant by substantially homogeneous mixture, substantially non-expanded, substantially non-cellular structure, and not substantially dextrinized. In addition, the present specification provides clear guidance to those skilled in the art as to mixing and extrusion conditions for obtaining a substantially homogenous mixture, to obtaining a substantially non-expanded, non-cellular structure, and avoiding substantial dextrinization of starch where exemplary specific densities are provided and conditions for avoiding excessive dextrinization are provided. It is accordingly submitted that the rejection on the grounds that the term "substantially" is indefinite should be withdrawn.

Examiner's Response

The term substantially adds a degree of variation. Applicant's arguments that one of ordinary degree in the art would understand this term in light of the specification is not persuasive because when reading the specification, there is no definition as to what

degree of variation the term "substantially" encompasses. In light of the specification, one would not know, for example, what degree of dextrinization would fall within the limits of the instant claims because the limits are not defined, such as 0% detrinization or 10% dextrinization. This is also the case for the homogeneity, non-expanded nature and non-cellular structure of the compositions. Further, Applicant defines "substantially dextrinized" with the term "excessive", which also renders the term indefinite because it is a relative term and it is not defined as to what degree is encompassed by the term "excessive".

Claim Rejections - 35 USC § 112 – Indefiniteness (Previous Rejection)

Claims 31, 59, 108 and 109 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's Arguments

Applicant argues, polyvinyl acetate and derivatives thereof, and modified starches are well known to those skilled in the art, as evidenced by Newton et al (USP 4,938,967) at col. 8 lines 61-65, and col. 9 lines 18-29, and Wittwer et al (USP 4,738,724) at col. 7 line 67 to col. 8 line 24.

Examiner's Response

Although polyvinyl acetate is definite, the term derivative is not. The term "derivative" is indefinite because it is unclear how far one can deviate from the parent compound without the "derivative" being so far removed therefrom as to be a completely different compound. Further, based on the instant specification, it is also not clear what "derivatives" are suitable for use in the instant invention. See the related rejection in the "Written description" section supra.

In claims 31, 59, 108 and 109, the term "modified starch" is indefinite because it is unclear how far one can deviate from the parent compound without the "modified" being so far removed therefrom as to be a completely different compound. Applicant has provide little guidance as to how one would be able to determine when the modification is so far removed that is no longer considered a "modified starch". See the related rejection in the "Written description" section supra.

Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)

1) Claims 25, 27-30, 34, 35, 37-40, 46, 52, 54-58, 61, 62, 64-67, 73, 75, 81-83, 85, 91, 92, 93, 95-97, 101, 103, 105, 108 and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newton et al. (4,938,967) in view of Lay (US 5,095,054).

Newton et al. disclose pharmaceutical compositions. The dosages are preferably capsules that contain one or more units. Density of conventional tablets and pellets is usually about 1.0 to 1.5 g/ml (1000 to 1500 g/liter) (col. 1, lines 11-13), encompassing claim 34. Selection of the binder determines the rate of release of the active ingredient (col. 1, lines 19-21). The dosage may be a plurality of pellets having a dimension below

about 2 mm, encompassing claims 28 and 55. The pellets have a shape that is spherical (col. 7, lines 48-57). The active ingredient comprises 0.0001 to 45% of the compositions (col. 10, lines 30-35). Various active agents may be used such as tonics (encompassing claim 93), anti-inflammatory, enzymes and anti-viral agents (col. 13 to col. 14, line 48). The pellets may comprise a matrix binder and a coating. These serve to control the release of the active. Binders include polymers such as starch and cellulose (col. 8, lines 53-68). Generally water is added to the compositions to aid in pelletisation (col. 11, lines 37-39), encompassing a water plasticizer. The matrix binder may comprise 50% of the particles (col. 10, lines 22-25). Each pellet may comprise a homogeneous blend of the active, the weighing material and the matrix binder components (col. 10, lines 58-60).

The reference discloses the use of plasticizers such as water in the compositions and thus it would appear that the presence of a plasticizer would lead to a plasticized mass.

The reference differs from the instant claims insofar as it does not disclose the exact amounts of matrix material or encapsulant as recited in the instant claims.

Newton et al. disclose the active may comprise 0.0001 to 45% of the compositions. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Therefore it would have been obvious to have used 1 to 85%, 5% to 50%, 3% to 50% and 5% to 20% of encapsulant (active agent) consistent with the In re Peterson decision.

In regards to the amounts recited in the instant claims such as the amount of matrix material, this is a result effective variable. The matrix material controls the release of the active and the active results in achieving the desired effect for the desired treatment. That being said, it would take no more than routine skill in the art to adjust the amount of matrix binder in the pellets to achieve the desired active release profile including the amount of active released in an aqueous or gastric juice environment as recited in claims 38 and 65.

In regards to the starch being "not substantially dextrinized", Applicant has asserted that detrinzation occurs during the heating process, thus it is reasonable to conclude that the starches of the reference are "not substantially dextrinized" because they do not appear to be heated. Further, considering that "substantially dextrinized" is not defined, it is unclear what degree of dextrinization is encompassed by the instant claims. See indefiniteness rejection above.

2) It is noted the instant claims recite a "plasticized mass" and not "a plasticized mass obtained by heating the material". Thus it is believed that Newton meets the limitations of the instant claims. For *arguendo* in the case that the "plasticized mass" is obtained by heating the matrix material in the presence of a plasticizer such as water, the following rejection is made.

Claims 25-31, 34, 35, 37-40, 46, 50, 52-59, 61, 62, 64-67, 73, 75, 79, 81-83, 85, 91, 92, 93, 95-97, 101, 103, 105, 108 and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newton et al. (4,938,967) in view of Lay (US 5,095,054).

Newton et al. is discussed above and differs from the instant claims insofar it does not disclose the starch is plasticized by heating.

Lay et al. disclose polymer compositions comprising starch that may be used to deliver pharmaceutical compositions or agriculturally active agents for subsequent release applications (col. 48, lines 13-19). The compositions comprise a) starch, b) a polymer and c) a water-insoluble thermoplastic polymer (Abstract). The compositions are heated with water (see Examples), which encompasses a plasticizer comprising water. These compositions form articles having dimensional stability and enhanced physical properties. Starches used include those from wheat and rice. Mixtures of starch may be used such as modified starches such as gelatinized or cooked starches, encompassing claims 26 and 53. The starch comprises at least 50% or more of the entire composition (col. 39, lines 7-14). Examples of lubricants are stearates of aluminum, calcium, magnesium and tin as well as talc, silicones, and the like, which may be present in concentrations of about 0.02 to about 5% based upon the weight of the total composition (col. 47, lines 9-13) encompassing claims 31 and 59. Additives include synthetic polymers, most preferably, are polyacrylic acid esters, polymethacrylic acids, polymethacrylic acid esters, polyvinyl alcohols and polyvinyl pyrrolidone (col. 46, lines 54-56), encompassing claims 50 and 79. The compositions may be formulated into granules and powders (col. 47, lines 66-68).

The reference differs from the instant claims insofar as it does not disclose the amount of pharmaceutical that may be added to the compositions, the amount of the composition in the final product or the size of the granules made from the composition.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art to have used a heated plasticized starch matrix in the formulations of Newton et al. motivated by the desire to use a composition that forms articles having dimensional stability and enhanced physical properties suitable for use in pharmaceutical formulations for delivering actives, as disclosed by Lay et al and supported by MPEP 2144.07.

It would have been obvious to have coated the actives before incorporating them into the matrix of Lay et al. motivated by the desire to add an additional control release mechanism for the active agent as suggested by the teachings of Newton et al.

Newton et al. disclose the active may comprise 0.0001 to 45% of the compositions. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Therefore it would have been obvious to have used 1 to 85%, 5% to 50%, 3% to 50% and 5% to 20% of encapsulant (active agent) consistent with the In re Peterson decision.

In regards to the amounts recited in the instant claims such as the amount of matrix material, this is a result effective variable. The matrix material controls the release of the active and the active results in achieving the desired effect for the desired

treatment. That being said, it would take no more than routine skill in the art to adjust the amount of matrix binder in the pellets to achieve the desired active release profile including the amount of active released in an aqueous or gastric juice environment as recited in claims 38 and 65.

Lay discloses temperature ranges and pressure up to 165 degrees C (Example (b-2)-1) similar to those disclosed by the instant specification up to 160 degrees C. Thus it is reasonable to conclude that the starches used by Lay are not “substantially dextrinized”. Further, considering that “substantially dextrinized" is not defined, it is unclear what degree of dextrinization is encompassed by the instant claims. See indefiniteness rejection above.

3) Claims 42, 69, 70, 84 and 108-110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newton et al. (4,938,967) in view of Lay et al. (US 5,095,054) as applied to claims 25-31, 34, 35, 37-40, 46, 50, 52-59, 61, 62, 64-67, 69, 73, 75, 79, 81-83, 85, 91, 92, 93, 95-97, 101, 103, 105, 108 and 109 in further view of Jane et al. (US 5,397,834).

Newton et al. and Lay et al. differ from the instant claims insofar as they do not disclose the wheat used as a starch source is durum wheat.

Jane et al. disclose biodegradable thermoplastic components made of the reaction of a starch aldehyde with protein. Suitable starches include those derived from durum wheat (col. 4, lines 41-50). The reference differs from the instant claims insofar

as it does not disclose the thermoplastic compositions are formulated into discrete particles comprising an active agent.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art to have used wheat durum as the wheat in the compositions of the combined teachings of Newton et al. and Lay et al. motivated by the desire to use a wheat comprising starch suitable for making thermoplastic compositions as disclosed by Jane et al. and supported by MPEP 2144.07.

Claims 25-31, 34, 35, 37-40, 42, 46, 50, 52-59, 61, 62, 64-67, 69, 70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103, 105 and 108-110 are rejected.

Claim 94 are withdrawn.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612